

Immunoprophylaxis in Healthcare: Human Rights Context

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Abstract

Author has addressed the topic of immunoprophylaxis in health care via the context of human rights. The author analyses every human's rights to refuse any medical service, including immunisation, as well as the rights of a person to receive health care in connection with the prevention of infectious diseases. The raised issue deems topical and binding.

Keywords: immunoprophylaxis, healthcare, principle of proportionality.

Introduction

In Ukraine as well as in most member states of the European Union, any medical service, including diagnostic or preventive ones, requires a patient's informed voluntary consent and, as a consequence, it appears that a person has the right to refuse immunoprophylaxis by means of vaccination. In particular, Art. 5 of the Convention on Human Rights and Biomedicine determines that

“an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.” [2]

Art. 6 proclaims that where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by the law [2]. At first sight, a person allegedly has the right to take charge of their private life refusing medical intervention or preventive measures for whatever reason. However, analysis of key international documents, including such a source of law as judgments

of the European Court of Human Rights (ECtHR), leads to the conclusion that such an interpretation is imperfect. This is because lawyers look into such type of medical services as immunoprophylaxis mainly from the perspective of private law dimension of a person's other rights, in particular, the right to education, the right to childhood, the right to work, as well as the freedom of religion and conscience. Thus, they disregard not only the content of international legal instruments on protection of human rights and fundamental freedoms, but also practice of the European Court of Human Rights concerning essence of the legal nature of limiting patients' rights as to consent or refusal of medical intervention to eliminate threat of harm to the third party's health. Meanwhile, the third party's rights should also be taken into account in the context of what is stated in Art. 2 of the Universal Declaration of Human Rights which provides that everyone is entitled to all the rights and freedoms set forth in this Declaration [21]. However, this is where the problem arises with application of the principle of proportionality which allows the judicial bodies to reason their judgments consistently and in detail [1].

Scientific works by leading experts in medical and pharmaceutical law as well as current legislation have been used in the research.

The issues of protection of patients' rights and pharmaceutical activities have been studied by the following scholars, namely, V. Tatsiy [19], N. Gutorova [10], A. Harkusha [11], Y. Hrekov [12], A. Olefir [15], A. Kotvitska [13], A. Soloviov [16], L. Udovyka [17] and other well-known experts [14]; however, insufficient attention has been paid to the issues of judicial consideration of cases involving protection of patients' rights, since only quite recently medical and pharmaceutical law as a whole has become the subject of scientific research in the domestic legal science.

Methodology of this research is based on organic combination of general scientific and special legal methods of studies, among which there are principles of objectivity, some techniques of a logical method, systemic and structural-functional methods, a method of legal simulation. Exactly, systematic method is applied to perform system analysis of the current legislation which regulates judicial consideration of cases involving protection of patients' rights. A structural-functional method allows revealing the main constituents of judicial considerations of the relevant category. A method of legal simulation is applied to formulate proposals for improving the existing legislation and practice of judicial consideration of cases involving protection of patients' rights.

Thus, assessment of third party's right to health and other people's rights consisting in provision of such rights and freedoms as the right to education, childhood and religion should be considered through the principle of proportionality or balancing.

Results and Discussion

Proportionality is the key concept to understanding how law operates. This comes from Art. 8 of the European Convention on Human Rights and Fundamental Freedoms (ECHR). The Convention is protected by the European Court of Human Rights, which was established in 1959 [1]. The principle of proportionality is to be acknowledged as one

of the plentiful “safety devices” able to assist in protecting a particular person against lawlessness or unjustified abuse of the power by public servants authorised to apply procedural coercive measures [9]. Balancing is in vogue in Europe, Canada, India, South Africa, and elsewhere; courts invoke balancing as the proper method of human rights adjudication. The European Court of Human Rights, by its own admission, routinely balances human rights against each other and against conflicting public interests and, in many countries, proportionality has been elevated, implicitly, to a basic constitutional principle [20]. At the same time, judgments of the ECtHR are consistent with both basic provisions of the European Convention for the Protection of Human Rights and Fundamental Freedoms and constitutional principles of European countries.

One of the current problems in ensuring the right to health is an ambiguous attitude towards the constituent part of this right, namely, immunoprophylaxis on the part of the public.

Meanwhile, most medical experts claim that immunoprophylaxis has been demonstrated to be a highly efficacious strategy in the primary prevention of disease, and most European countries impose mandatory vaccination according to the vaccination schedule. In addition, individuals and communities understand the value of vaccines and demand immunisation as both their right and responsibility [6].

Thus, in pursuance of urgent vaccination regulations dated June 7, 2017, in the Italian Republic, according to the National Immunisation Schedule, twelve vaccine types for children under the age of sixteen are mandatory and free of charge in order to ensure public health protection and preservation of epidemiological safety, prevention and vaccination coverage, as well as in compliance with European and international commitments.

In case of non-compliance with the vaccination obligation, parents incur a monetary liability, and local public health authorities must report failure to comply with the vaccination obligation to the prosecutor [3].

In its turn, Section 20 of the Act on the Reform of the Communicable Diseases Law (Communicable Diseases Law Reform Act) establishes that a Standing Vaccination Commission shall be established at the Robert Koch Institute. The Commission adopts Rules of Procedure that are subject to the consent of the Federal Ministry for Health. The Commission issues recommendations on the conduct of vaccinations and other measures for specific prophylaxis of communicable diseases and develops criteria for the distinction between a normal post-vaccinal reaction and a health impairment the degree of which exceeds that of a normal post-vaccinal reaction. Besides, supreme health authorities of the Länder can determine that health offices conduct vaccinations or other measures of specific prophylaxis against certain communicable diseases free of charge [6]. Or, for example, in the USA, if a child is denied school attendance because she is not immunised and the parent does not qualify for a lawful exemption, the parent can be prosecuted for failing to meet the requirements of compulsory education for her state, but cannot claim the fact that the school denied her child entrance because she was unimmunised as a defense [18]. According to Polish law, part of preventive vaccinations is obligatory and

another part is recommended. Vaccinations are mandatory for everyone (both insured persons, as well as uninsured) and funded from public funds. Funding for recommended vaccination is varied. In the case of their implementation by the primary care provider selected by the patient, the patient covers only the cost of the vaccine preparation and the service provider bears the costs of qualification tests and implementation of vaccination. If a patient decides for vaccinations at a commercial point of vaccination, they cover their costs in full [8].

Thus, in most developed countries, there is legal and regulatory leverage over their citizens concerning enforcement of the right to health by means of immunoprophylaxis, which is generally confirmed by the European Vaccine Action Plan 2015–2020 (EVAP). The WHO Regional Office for Europe. Background Plan affirms that immunisation has brought about a remarkable reduction in child mortality in the WHO European Region over the past few decades. Today, nine of every ten children in the Region receive at least a basic set of vaccinations during infancy, and as a result lead healthier, more productive lives [22].

Despite sufficient legal framework and other levers of influence concerning evasion of immunoprophylaxis, in some cases domestic courts generally misinterpret international acts referring to them in terms of enforcing a third party's right to health or another person's rights and freedoms.

To clarify the nature of these deficiencies, first it is necessary to analyse the practice of the European Court of Human Rights (ECtHR), especially since its judgment is a source of law for our country. But here again, proportionality is one of the main principles scrutinising actions adopted by national authorities which restricts rights under the European Convention for the Protection of Human Rights and Fundamental Freedoms of November 4, 1950 [5].

As far as vaccination is regarded, there are numerous references to the same judgments of the ECtHR, for instance, they often refer to the case of *Jehovah's Witnesses of Moscow and Others vs. Russia* (Application No. 302/02), Strasbourg, June 10, 2010. Nevertheless, even commenting on this case, most lawyers focus only on international acts used by the Court, but not on the principles and methods of evaluating materials as well as conclusions. In other words, in this case, when addressing the issues of vaccination, the decision-making principles and, in some cases, specific conclusions of the very nature of the vaccination itself are important for lawyers. Some conclusions are also important, in particular, that in paragraph 136, where it is stated that "it was emphasised that free choice and self-determination were themselves fundamental constituents of life and that, absent of any indication of the need to protect third parties – for example, mandatory vaccination during an epidemic, the State must abstain from interfering with the individual freedom of choice in the sphere of healthcare, for such interference can only lessen and not enhance the value of life." However, preliminarily it is necessary to use paragraph 85, which refers to the precedent heard by the Ontario Supreme Court in Canada:

“The state undoubtedly has a strong interest in protecting and preserving the lives and health of its citizens. There clearly are circumstances where this interest may override the individual’s right to self-determination. For example, the state may, in certain cases, require that citizens submit to medical procedures in order to eliminate a health threat to the community.” [4]

In Ukraine cases of mandatory vaccination are heard by courts in both civil and administrative proceedings. Their judgments are rather controversial and often not properly reasoned. However, analysis of these cases makes it possible to classify patients who refuse to be vaccinated legally for several reasons, in particular: 1) for health reasons; 2) according to religious beliefs; 3) because of neglecting their duties as parents which leads to serious illnesses entailing significant harm to a child’s health; 4) due to distrust of the competence of medical personnel.

Separate group of patients are persons that for distinct reasons refuse to be vaccinated in a non-legal way by obtaining a fake certificate of vaccinations issued by a healthcare practitioner.

If we consider vaccination as one of health services, the right to this type of service is to be considered in the context of consent to medical intervention. In other words, a patient’s informed consent is required to use diagnostic, preventive and treatment methods.

An example of contradictory ideas as to the principles of law can be observed within judgments in various but similar cases of one of the courts in Volyn region.

Volyn District Administrative Court in the case No. 2a-18037/09/0370 of July 2, 2009, refusing to satisfy the claim for the invalidation of the application for removal from attending a child at a pre-school educational institution, substantiated his decision by the fact that Part 2 of Art. 15 of the Law of Ukraine “On Protection of the Population against Infectious Diseases”, which explicitly stipulates that children who have not received preventive vaccinations according to the schedule of vaccinations, visits to children’s facilities are not allowed. Furthermore, since in pursuance of Part 2 of Art. 11 of the Law of Ukraine “On Pre-School Education”, a pre-school institution shall create safe and harmless conditions for children’s development, education and training, mode of operation, conditions for physical development and health promotion in accordance with sanitary and hygienic requirements and ensure their compliance, therefore, attending pre-school educational institutions by children who have not undergone mandatory preventive vaccinations will violate the rights of other children (who have undergone such vaccinations) to safe and harmless conditions of development, education and training in accordance with sanitary and hygienic requirements.

Two other cases, No. 2a-6501/09/0370 (the ruling dated March 16, 2009) and No. 2a/0370/2586/11 (the ruling dated October 12, 2011) were heard by Volyn District Administrative Court by a different panel of judges. The main feature there is that they were both tried by the same panel of judges and they both resulted in opposite judgments.

In the first case (the ruling dated March 16, 2009) on behalf of other persons, the prosecutor of the city of Lutsk appealed to the sanitary epidemiological service to declare illegal and cancel the application for removal from attending the secondary school of I–III steps of children not received vaccinations. The claims were motivated by virtue of Art. 53 of the Constitution of Ukraine, according to which everyone has the right to education and Art. 3 of the Law of Ukraine “On Education” which stipulates that citizens of Ukraine shall have the right to free education in all public educational institutions regardless of their gender, race, nationality, social and economic status, type and nature of their activities, world views, belonging to parties, attitude towards religion, religious conscience, state of health, place of residence and other circumstances. At the same time, the court did not take into consideration the reference of the Sanitary Epidemiological Service to the fact that failure to observe requirements of the Law of Ukraine “On Protection of Population against Infectious Diseases” which recognises vaccinations for prevention of tuberculosis to be mandatory may lead to violation of other people’s rights, in this case, children studying with the plaintiffs’ children at the secondary school of I–III degrees, since as it was stated in the court session, all the above-mentioned children studying at this school had undergone a medical examination and were declared healthy, which was also not objected by the defendant’s representatives.

In this case, there is a misconception as even if the court used the principle of proportionality it was mistaken in such situation. Due to misunderstanding of the principle of correspondence, the court ignored the algorithm of conducting the proportionality test.

In the other case No. 2a/0370/2586/11 (the ruling dated October 12, 2011), the same panel of judges heard a complaint filed against the Medical Advisory Commission at the children’s clinic of Kovel City Medical Association of the Public Health Department of Volyn Regional State Administration on recognising actions regarding refusal to issue a permit to attend a pre-school educational institution. The plaintiff motivated his claims by the child’s right to education which is provided for by the Constitution of Ukraine whose rules are rules of direct effect, the ruling of the Constitutional Court of Ukraine which contains an official interpretation of access to education as a constitutional guarantee of the right to education on the principles of equality, and therefore, restriction of this right is possible only in conditions of emergency or martial law, otherwise, Article 15 of the Law of Ukraine “On Protection of Population against Infectious Diseases” as to prohibition of attending pre-school educational institutions by children who have not undergone preventive vaccinations contradicts the Constitution of Ukraine.

Denying the claim in accordance with parts 1, 6, 7 of Art. 12, part 2 of Art. 15 and Art. 41 of the Law of Ukraine “On Protection of the Population against Infectious Diseases”, the court noted that preventive vaccinations against diphtheria, pertussis, measles, poliomyelitis, tetanus, tuberculosis are mandatory and included in an immunisation schedule, and children who have not undergone preventive vaccinations according to the immunisation schedule cannot attend children’s institutions. Persons responsible for violating the legislation on protection against infectious diseases incur a liability in accordance with the laws of Ukraine.

In view of the content of the mentioned rule, the court considers the plaintiff's reference to discrimination, which is in denied access to education or any violations of the child's right to education, to be not true and thus the person's claims are unacceptable.

Even though the court pronounced a proportional judgment, unfortunately, it still did not comply with proportionality test. Use of the principle of legality by the court of this instance was more likely to be appropriate, although it would have been appropriate for a higher court to use the principle of the rule of law. The problems of legal linguistics in the context of the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) of November 4, 1950, which enunciates the principle of the rule of law, were discussed by the Parliamentary Assembly of the Council of Europe (see: Resolution No. 1594 (2007)). The Parliamentary Assembly drew attention to the fact that in some recent democracies in Eastern Europe, the main trends in legal thinking foster an understanding of the "rule of law" as "supremacy of statute law", i.e. primacy of law.

In another case, No. 2-a/337/3087/17 (the ruling dated October 09, 2017), the court heard a person's complaint filed against the Territorial Education Department of Khortytzia district of the Education and Science Department of Zaporizhia City Council on recognising actions as illegal regarding denied enrollment of a child in a pre-school educational institution, which is a kindergarten. The plaintiff refers to the fact that for reasons of the child's health security, presumed low-quality of free vaccine, high level of child mortality after vaccination, religious beliefs and principles, the child's father and she herself refused to provide preventive vaccinations to their son and assumed all the responsibility for the children in the event of negative health consequences in this regard.

The court upheld the claim reasoning it with provisions of paragraphs 1 and 2 of Art. 3 of the Convention on the Rights of the Child ratified by the Verkhovna Rada of Ukraine on February 27, 1991, provisions of Arts. 3, 12 of the Law of Ukraine "On the Protection of Childhood", which practically reproduce provisions of Art. 2 of the Convention on the Rights of the Child of 20 November, 1989, amended by the UN General Assembly Resolution 50/155 of December 21, 1995, ratified by the Resolution of the Verkhovna Rada of Ukraine No. 789-XII of February 27, 1991, as well as in accordance with Art. 9 of the Law of Ukraine "On Pre-School Education" and Protocol No. 1 of the Council of Europe to the Convention for the Protection of Human Rights and Fundamental Freedoms, the Universal Declaration of Human Rights, the European Social Charter, Arts. 8, 19, 46 of the Constitution of Ukraine.

Case, No. 286/2479/16-a (the ruling dated October 11, 2017), in fact, is based on similar circumstances according to a claim filed against a pre-school educational institution No. 10 of the town of Ovruch, Ovruch District Council, Zhytomyr region. The court rendered a judgment with similar reasoning in favour of plaintiffs who refused to provide vaccination to their child. Case No. 286/5524/14-a (the ruling dated September 22, 2014) is based on similar circumstances according to a claim filed against a pre-school educational establishment regarding enrollment of a child without scheduled vaccinations. The court upheld the claim reasoning it as it had been performed in the above example.

An interesting case was carried out by the Court of Appeal of Khmelnytskyi region (No. 682/1692/17) concerning denying a person of attending a pre-school educational institution in connection with violation of the vaccination schedule.

In its ruling, the court noted that any right objectively corresponds with duties and since the right to pre-school education is linked by the legislator with the duty to undergo preventive vaccinations (which guarantee safety of both the child and people around him/her), a certificate issued by a medical center which states that the child is healthy and can attend an institution cannot substitute for a conclusion of a medical advisory committee at a medical facility of possibility of attending a pre-school educational institution by children whose parents refuse vaccinations. At the same time, the judicial body takes into account that the defendant's offense does not deprive them of the right to education since they can receive it in other forms.

The right to education declared by Art. 53 of the Constitution of Ukraine provides for certain actions done by this person. In accordance with clause 6 of the Regulations on Pre-school Institution, such actions include submission by a child's parents of an application for enrollment of a child in a pre-school institution, a medical certificate of his / her state of health, a certificate of epidemiological environment issued by a district doctor, a child's birth certificate.

However, rendering judgments in favour of one person neglecting other children's rights to health is evidence of incorrect understanding of the principles of justice by judges and lawyers. And such actions are treated as a consequence of "blind" copying of the ECHR requirements without appropriate clear understanding of the practice of the ECtHR.

Conclusions

The given data make it obvious that in some cases the state may legitimately restrict certain rights and freedoms by carrying out mandatory immunoprophylaxis, but it is necessary to prove that such restriction of the human right to freedom of choice in healthcare is as follows: 1) provided by law and carried out in compliance with it; 2) consistent with such legitimate objectives as public health; 3) an absolutely necessary measure to achieve these goals (conformity); 4) necessary in view of lack of less rigid ways to achieve these goals (auxiliary character); 5) conducted not arbitrarily, but fairly and without discrimination.

The above considerations, combined with analysis of the provisions of universal and regional international health-care instruments, give grounds for distinguishing the concept of understanding the right to health as an absolute subjective natural right. This right is directly related to public interests and is not limited to medical intervention, but involves the use of a number of legal, organisational, social measures aimed at comprehensive provision of public health, among which preventive measures to prevent spread of infectious diseases, in particular immunoprophylaxis (immunisation).

Being a component of state measures in healthcare, immunoprophylaxis has been formed as a result of determining social aspect as the main cause of spread of infectious diseases. That is why most international acts identify prevention and treatment of epidemic, endemic diseases, as well as preventive treatment among top priorities in public health.

The right of a person to freedom of choice in the field of health protection in relation to immunisation meets the duty of the state, firstly, to create conditions for free and unimpeded exercise of such a right by adopting positive measures for the organisation of the system for prevention of infectious diseases, and, secondly, in exceptional cases to take measures to restrict exercise of this right in order to ensure realisation of public interests, national security by, in particular, mandatory vaccination.

Imūnprofilakse veselības aprūpē: cilvēktiesību konteksts

Kopsavilkums

Pētījums ir veltīts imūnprofilakses problēmām cilvēktiesību aizsardzības kontekstā. No vienas puses, izmantojot proporcionalitātes principu, autors analizē cilvēka tiesības atteikties no medicīniskiem pakalpojumiem, tostarp vakcinācijas. No otras puses, tiek pētītas citu cilvēku tiesības uz veselības aprūpi saistībā ar infekcijas slimību profilaksi. Autors izmanto Eiropas Cilvēktiesību tiesas praksi, lai argumentētu izdarītos secinājumus.

Atslēgvārdi: medicīniskā palīdzība, medicīniskais dienests, informēta piekrišana, imūnprofilakse, proporcionalitātes princips.

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